General

Guideline Title

Combined hormonal contraception.

Bibliographic Source(s)

Clinical Effectiveness Unit. Combined hormonal contraception. London (UK): Faculty of Sexual and Reproductive Healthcare; 2011 Oct. 28 p. [195 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. First prescription of combined oral contraception. London (UK): Faculty of Family Planning and Reproductive Health Care; 2007 Jan. 21 p. [186 references]

Recommendations

Major Recommendations

Definitions of the grades of recommendation, based on levels of evidence (A-C, Good Practice Point), are provided at the end of the "Major Recommendations" field.

How Does Combined Hormonal Contraception (CHC) Work?

- Women can be informed that the bleed experienced during the hormone-free interval or placebo week of pill taking is due to withdrawal of hormones rather than a menstrual bleed. (Grade C)
- Health professionals may wish to advise women about the use of extended or continuous regimens of CHC but should be aware that such use is off license. (Grade C)

How Do Each of the CHC Methods Compare to One Another?

- Women can be informed that the efficacy of all CHCs is generally similar. (Grade B)

What Assessments Are Needed Before Prescribing a Woman CHC for the First Time?

- Health professionals should take a detailed history from women requesting CHC including medical conditions such as migraine, drug use, family medical history, and lifestyle factors such as smoking, and should recheck the history at least annually. (Good Practice Point)
- A blood pressure recording should be documented for all women prior to first prescription of CHC. (Grade C)

- Body mass index (BMI) should be documented for all women prior to first prescription of CHC. (Good Practice Point)

What Drug Interactions Are Important to Consider in Relation to CHC?

- Additional contraceptive precautions are not required when antibiotics that do not induce enzymes are used in conjunction with CHCs. (Grade C)
- Women who do not wish to change from a combined method while on short-term treatment with an enzyme-inducing drug (and for 28 days after stopping treatment) may opt to continue using a combined oral contraception (COC) containing at least 30 µg ethinylestradiol (EE), the patch or ring along with additional contraception. An extended or tricycling regimen should be used and the hormone-free interval shortened to 4 days. Additional contraception should be continued for 28 days after stopping the enzyme-inducing drug. (Good Practice Point)
- With the exception of the very potent enzyme inducers rifampicin and rifabutin, women who are taking an enzyme-inducing drug and who do not wish to change from COC or use additional precautions may increase the dose of COC to at least 50 µg EE (maximum 70 µg EE) and use an extended or tricycling regimen with a pill-free interval of 4 days. (Good Practice Point)
- Women taking lamotrigine (except in combination with sodium valproate) should be advised that due to the risk of reduced seizure control whilst on CHC, and the potential for toxicity in the CHC-free week, the risks of using CHC may outweigh the benefits. (Grade C)
- Women should be advised that ulipristal acetate (UPA) has the potential to reduce the efficacy of hormonal contraception. Additional precautions are advised for 14 days after taking UPA (9 days if using or starting the progestogen-only pill [POP], 16 days for estradiol valerate/dienogest pill) (outside product licence). (Good Practice Point)

Risks, Non-contraceptive Health Benefits and Side Effects

Health Risks

Venous Thromboembolism (VTE)

- Health professionals should be aware that compared to non-users, the risk of VTE with use of CHC is approximately doubled but that the absolute risk is still very low. (Grade B)
- Health professionals prescribing CHCs should be guided by the individual's own personal preference, risk of VTE, any contraindications, possible non-contraceptive benefits and experience with other contraceptive formulations. (Grade C)
- A personal history of VTE or a known thrombogenic mutation are conditions that represent an unacceptable health risk if CHC is used. (Grade C)
- For women with a family history of VTE, a negative thrombophilia screen does not necessarily exclude all thrombogenic mutations. (Grade C)
- A thrombophilia screen is not recommended routinely before prescribing CHC. (Grade C)

Cardiovascular Disease and Stroke

- Use of CHC in women aged ≥35 years who smoke is not recommended. (Grade B)
- Health professionals should be aware that there may be a very small increase in the absolute risk of ischemic stroke associated with CHC use. (Grade B)
- Migraine with aura is a condition for which the use of CHC presents an unacceptable health risk (UK Medical Eligibility Criteria for Contraceptive Use [UKMEC 4] [see Table 2 in the original guideline document]). (Grade C)
- The risks of using CHC in women with properly taken blood pressure (BP) which is consistently elevated generally outweigh the advantages. Systolic BP ≥160 mmHg or diastolic BP ≥95 mmHg is a condition that represents an unacceptable health risk if CHC is used (UKMEC 4 [see Table 2 in the original guideline document]). (Grade B)
- The risk of using CHC in women with a BMI ≥35 kg/m^2 usually outweighs the benefits (UKMEC 3 [see Table 2 in the original guideline document]). (Grade B)

Breast Cancer

- Health professionals should be aware that any risk of breast cancer associated with CHC use is likely to be small, and will reduce with time after stopping. (Grade B)

Cervical Cancer

- Health professionals should be aware that CHC use may be associated with a small increase in the risk of cervical cancer which is related to duration of use. (Grade B)
- Health professionals should check that women coming for CHC are up to date with cervical cytology screening in accordance with

screening recommendations. (Good Practice Point)

Non-contraceptive Health Benefits

Mortality

- Women can be advised that CHC use does not appear to have a negative effect on overall mortality. (Grade B)

Ovarian and Endometrial Cancer

- Use of COC is associated with a reduced risk of ovarian and endometrial cancer that continues for several decades after stopping. (Grade B)

Acne

- Health professionals should be aware that CHC may help to improve acne. (Grade A)

Colorectal Cancer

- Health professionals should be aware that COC use is associated with a reduction in the risk of colorectal cancer and this may also apply to other CHCs. (Grade B)

Dysmenorrhoea and Heavy Menstrual Bleeding

- Health professionals should be aware that use of CHC may help to reduce menstrual pain and bleeding. (Grade C)

Menopausal Symptoms

- Women can be advised that CHC may reduce menopausal symptoms. (Grade C)

Side Effects

Unscheduled Bleeding

- Before starting CHC women should be advised about expected bleeding patterns both initially and in the longer term. (Good Practice Point)

Mood Changes

- Women can be advised that CHC may be associated with mood changes but there is no evidence that it causes depression. (Grade C)

Weight Gain

- Women can be advised that the current evidence does not support a causal association between CHC and weight gain. (Grade B)

CHC Whilst Traveling or at High Altitude

- Women taking CHC should be advised about reducing periods of immobility during flights over 3 hours. (Good Practice Point)
- Women trekking to altitudes of >4500 m for periods of more than 1 week may be advised to consider switching to an alternative method. (Good Practice Point)

Definitions:

Grading of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

Clinical Algorithm(s)

An algorithm is provided in the original guideline document on advice for women missing combined oral contraceptive pills (except estradiol valerate/dienogest pill [Qlaira®]).

Scope

Disease/Condition(s)

Unintended pregnancy

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Nursing

Obstetrics and Gynecology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

- To provide evidence-based recommendations and clinical guidance on combined hormonal contraception (CHC)
- To update and replace previous Faculty of Sexual and Reproductive Healthcare guidance

Target Population

Women considering the use of combined hormonal contraception (CHC)

Interventions and Practices Considered

1. Clinical history including medical, family, and drug history and assessment of cardiovascular risk factors and migraines
2. Blood pressure measurement and body mass index assessment
3. Assessment of medical eligibility for contraceptive use
4. Counseling and educating patients on risks and benefits of combined hormonal contraception (CHC)
5. Advising women when to start CHC in different circumstances, helping them to choose their first CHC, and giving instructions regarding missed pills and situations where efficacy may be reduced
6. Consideration and management of drug interactions
7. CHC use while traveling or at high altitude
8. Follow-up visits

Major Outcomes Considered

- Contraceptive efficacy (pregnancy rates)
- Side effects of combined hormonal contraception
- Non-contraceptive health benefits

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence is identified using a systematic literature review and electronic searches were performed for MEDLINE (CD Ovid version) (1996–2011); EMBASE (1996–2011); PubMed (1996–2011); The Cochrane Library (to 2011) and the US National Guideline Clearinghouse. The searches were performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library was searched for relevant systematic reviews, meta-analyses and controlled trials relevant to combined hormonal contraception. Previously existing guidelines from the Faculty of Sexual and Reproductive Healthcare (FSRH) (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, were also searched.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

Rating Scheme for the Strength of the Evidence

Not stated

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Recommendations are graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organisations. The clinical recommendations within this guidance are based on evidence whenever possible. Summary evidence tables are available on request from the Clinical Effectiveness Unit (CEU).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

A multidisciplinary group is appointed by invitation to the main stakeholders. The Clinical Effectiveness Unit (CEU) and multidisciplinary group revise the key questions, and a systematic literature review, critical appraisal, and development of evidence tables is performed by the CEU researcher.

Draft one of the guidance document is written by the CEU. The multidisciplinary group holds a one-day meeting to peer review the document and provide written feedback. Draft two of the guidance document is prepared by the multidisciplinary group, the Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Committee (CEC) and two independent peer reviewers.

Draft three of the guideline is prepared, based on written feedback, and the multidisciplinary group is asked to take consensus process, after which draft four is prepared. This draft document is published on the Faculty Web site for 1 month for public consultation. Stakeholders are informed of this consultation process. All written feedback comments are reviewed by the CEU and FSRH CEC. The final draft is prepared, and the CEU's response to consultation comments is posted on the FSRH Web site.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations

A: Evidence based on randomised controlled trials

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Draft three of the guideline is prepared, based on written feedback, and the multidisciplinary group is asked to take consensus process, after which draft four is prepared. This draft document is published on the Faculty Web site for 1 month for public consultation. Stakeholders are informed of this consultation process. All written feedback comments are reviewed by the CEU and FSRH CEC. The final draft is prepared, and the CEU's response to consultation comments is posted on the FSRH Web site.

The final guidance document is published by the FSRH. Print copies are mailed to FSRH members and a Portable Document Format (PDF) version of the guidance is available on the FSRH Web site. Post-publication feedback is reviewed by the CEC and the web version is amended as and when necessary.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate use of combined hormonal contraception (CHC) to prevent unintended pregnancy
- Non-contraceptive benefits of CHC may include:
  - Reduction in menstrual pain and blood loss
  - Reduction in risk of ovarian cysts and benign ovarian tumours, ovarian cancer, endometrial cancer, and colorectal cancer
  - Reduction in menopausal symptoms
  - Improvement in acne

Potential Harms

- Side effects of combined hormonal contraception (CHC) may include increased risk of:
  - Breast cancer
  - Cervical cancer
  - Venous thromboembolism (VTE) (including deep vein thrombosis and pulmonary embolism)
  - Cardiovascular disease and stroke
- Enzyme-inducing drugs may reduce the efficacy of CHC.
- The risk of using CHC in women with a BMI $\geq 35 kg/m^2$ usually outweighs the benefits.
- Migraine with aura is a condition for which the use of CHC presents an unacceptable health risk.
- A personal history of VTE or a known thrombogenic mutation are conditions that represent an unacceptable health risk if CHC is used.

Qualifying Statements

Qualifying Statements

Qualifying Statements

Recommendations within this document are based on available evidence and consensus opinion of experts. They should be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2003 Oct (revised 2011 Oct)

Guideline Developer(s)

Faculty of Sexual and Reproductive Healthcare - Professional Association

Source(s) of Funding

Faculty of Sexual and Reproductive Healthcare

Guideline Committee

Clinical Effectiveness Unit

Composition of Group That Authored the Guideline

Guideline Development Group: Dr Pauline McGough (Joint Clinical Director, Sandyford, Glasgow); Ms Julie Craik (Researcher, Clinical Effectiveness Unit); Dr Louise Melvin (Director, Clinical Effectiveness Unit); Dr Fiona Boyd (FSRH Meetings Committee Representative; Associate Specialist, Highland Sexual Health, Raigmore Hospital, Inverness); Dr Lesley Craig (FSRH Clinical Effectiveness Committee representative; Associate Specialist, Square 13 Centre for Family Planning and Reproductive Health, Aberdeen); Dr Miranda Farmer (Member of RCGP Sex, Drugs and HIV Group; General Practitioner, Manchester Road Medical Centre, Knutsford); Professor Phil Hannaford (NHS Grampian Professor of Primary Care, Foresterhill Health Centre, Aberdeen); Mrs Lynn Hearton (FSRH Clinical Effectiveness Committee and user representative; Helpline and Information Services Manager, Family Planning Association, London); Dr Asha Kasliwal (Chair of FSRH Clinical Standards Committee; Clinical Director and Consultant in Community Gynaecology and Reproductive Health Care, Palatine Contraception and Sexual Health Service, The Hathersage Centre, Manchester); Dr Elizabeth Kennedy (Associate Specialist, Tayside Sexual and Reproductive Health Services, Ninewells Hospital, Dundee); Dr Ali Kubba (Consultant Community Gynaecologist, Mawbey Brough Health Centre, London); Dr James McVicker (FSRH Council representative; Clinical Director, Community Sexual Services LCH, Central Abacus, Liverpool); Dr Rashmi Ronghe (Subspecialty Trainee in Sexual and Reproductive Health, Sandyford, Glasgow); Dr Alison Vaughan (FSRH Council representative; Lead Specialty Doctor, Contraception and Sexual Health, Dorset Contraception and Sexual Health, Dorchester); Mrs Angela Wake (Nurse Lead, CASH Service, Plymouth and National Association of Nurses for Contraception and Sexual Health [NANCSH] Chairperson)

Administrative support to the CEU team was provided by Ms Janice Paterson.

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

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This guideline updates a previous version: Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. First prescription of combined oral contraception. London (UK): Faculty of Family Planning and Reproductive Health Care; 2007 Jan. 21 p. [186 references]

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Faculty of Sexual and Reproductive Healthcare Web site .

Print copies: Available from the Faculty of Sexual and Reproductive Healthcare, 27 Sussex Place, Regent's Park, London NW1 4RG

Availability of Companion Documents

Discussion points and questions for the first prescription of combined oral contraception developed by the Faculty of Sexual and Reproductive Healthcare are available at the end of the original guideline document .

In addition, auditable outcomes are available at the end of the original guideline document .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on July 5, 2005. This summary was updated by ECRI Institute on May 13, 2008. This NGC summary was updated by ECRI Institute on May 9, 2012.

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